UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In Re Pharmaceutical Industry Average Wholesale Price Litigation	
This Document Relates To: GOVERNMENT EMPLOYEES HOSPITAL ASSOCIATION and DISTRICT COUNCIL 37 HEALTH AND SECURITY PLAN TRUST, individually and on behalf of all others similarly situated, Plaintiff v. SERONO INTERNATIONAL, S.A., SERONO LABORATORIES, INC., SERONO, INC., RJL SYSTEMS, INC., AND RUDOLPH J. LIEDTKE, Defendants.	MDL No. 1456 C.A. No. 05-cv-11935 (PBS)

SECOND AMENDED CLASS ACTION COMPLAINT AGAINST SERONO INTERNATIONAL, S.A., SERONO LABORATORIES, INC., SERONO, INC., RJL SYSTEMS, INC., AND RUDOLPH J. LIEDTKE

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I. NATURE OF THE ACTION

1. This is a proposed national class action brought on behalf of consumers and third-party payors (self-insured employers, Taft-Hartley funds, non-profit and for-profit heath insurers, all of whom bear the ultimate risk for prescription drug expense) against Serono International, S.A., Serono, Inc., Serono Laboratories, Inc. (collectively "Serono"), RJL System, Inc. ("RJL"), and Rudoph J. Liedtke ("Liedtke") seeking damages and other monetary relief by reason of the Defendants' deceptive and illegal marketing, sales, and promotional activities for the prescription drug Serostim and other pharmaceutical products.

2. In 1996, Serono obtained accelerated approval from the U.S. Food and Drug Administration ("FDA") for Serostim for the sole purpose of treating AIDS wasting. At the time, AIDS wasting was the leading cause of death among AIDS patients. But just as Serono was bringing Serostim to market, other drug companies were bringing to market a new class of drugs known as protease inhibitors that dramatically improved treatment of AIDS. These drugs, when used in various combinations commonly known as an "AIDS cocktail," dramatically curtailed the replication of the HIV virus in HIV infected individuals. As a result of the discovery of this new treatment, the prevalence of HIV conversion to AIDS and associated conditions, including AIDS wasting, diminished and the cases in which Serostim treatment was medically necessary radically declined.

3. Faced with faltering demand for a drug that had become marginalized by new and superior therapies, Serono embarked on a campaign of criminal deceit, manipulation, kickbacks and fraud that caused physicians to write prescriptions for Serostim, and caused consumers and third-party payors to pay for Serostim prescriptions, even though taking Serostim was medically unnecessary and of no medical benefit to the patient.

4. Serono did not accomplish these deceptions on its own. Not only did Serono itself engage in acts of deceit, but it also contracted with medical device marketing firm RJL and its principal Liedtke to provide unapproved and unproven medical devices and software, and to develop fraudulent and misleading tests, that would fabricate data to support prescription of Serostim where no medical necessity existed, causing Serostim prescriptions to be written and paid for by consumers and third-party payors that provided Serostim patients with no medical benefit. Serono also paid inducements to physicians, including lavish all-expense paid trips to Cannes, France, in exchange for agreements by those physicians to prescribe Serostim, and paid pharmacies to provide lists of physicians who were likely to prescribe Serostim and for other unlawful purposes. Thus, Serono associated itself with a discrete, identifiable medical device maker, its principal, physicians, and others unknown to knowingly effectuate its deceptive and illegal marketing and promotional campaign to induce physicians to prescribe Serostim based on fraudulent diagnostic procedures in circumstances in which no proven medical necessity for the treatment existed, causing consumers and third-party payors to pay for unnecessary Serostim treatments that provided the patients with no medical benefit.

5. From September 1996 through at least January 2002, Serono and RJL engaged in a series of deceptive and illegal acts whose sole purpose was unlawfully to promote, market and sell Serostim in circumstances where the prescription of Serostim was not supported by proof of medical necessity, and where the prescription provided no medical benefit to the patients. The purpose of these schemes was fraudulently to cause consumers and third-party payors to pay for Serostim which the patients did not need and which provided them no benefit. All defendants, Serono sales consultants, physicians, and all others who

participated in these schemes knew or had reason to know that the objective of these schemes was deceptive and illegal. These schemes included:

6. *Medical Device Activities.* Promoting the use of unapproved, adulterated and unproven bioelectrical impedance analysis ("BIA") medical devices and computer software marketed by RJL and Liedtke to physicians which purported to calculate body cell mass wasting to fraudulently create a medical basis for prescription of Serostim; distributing these medical devices and computer software to physicians for the sole purpose of increasing the demand for Serostim; and training, authorizing and encouraging Serono sales representatives to administer the purported body cell mass wasting tests to AIDS victims, and to fraudulently manipulate or fabricate the results, to fraudulently promote the sale of Serostim.

7. *Physician Kickback Activities*. Paying illegal inducements and kickbacks to physicians to induce them to prescribe Serostim. Among other things, from March 1999 through December 1999, in an attempt to reverse the severe shortfall in sales of Serostim, Serono offered physicians in exchange for writing up to 30 new prescriptions of Serostim a lavish all-expenses paid trip to a medical conference in Cannes, France. Because each prescription encompassed a 12-week course of therapy that cost $21,000, the value of 30 prescriptions to be written by each doctor was $630,000. These were straight quid pro quo offers and Serono and the physicians knew they were illegal. Indeed, many of the physicians offered the payments turned them down, telling Serono sales representatives they viewed the payments as a "bribe." The Serono marketing department announced within the company that 10 physicians were "U.S. Invitees" to the Cannes conference with all expenses paid for them and their guest to attend. The 30 prescriptions each doctor was expected to write meant a total

value of approximately $6.3 million in sales. Illegal inducements also included payments of stipends and honoraria for fictitious speaking engagements and facilitating billing by physicians to third-party payors for fraudulent body cell mass wasting tests that the physicians themselves did not perform. The offer and payment of the kickbacks and inducements was intended by Serono to cause and did cause physicians to prescribe Serostim regardless of medical need or benefit, and was intended to cause and did cause consumers and third-party payors to pay for Serostim, in circumstances in which there was no medical necessity demonstrated, and no medical benefit conferred, on the patients taking Serostim.

8. *Gifting BIA Machines.* Providing other forms of inducements to physicians to prescribe Serostim, such as giving physicians BIA machines, as part of a purported study protocol.

9. *Over Prescribing Activities.* Fraudulently encouraging physicians to prescribe dosages of Serostim that the patients did not need or could not consume.

10. *Off-label Marketing Activities.* Marketing Serostim to physicians for the treatment of lipodystrophy, a separate condition involving weight gain in the mid-section and weight loss in the extremities, different from AIDS wasting, for which Serostim was not approved by the FDA, causing consumers and third-party payors to pay for Serostim in circumstances in which there was no medical necessity or medical benefit conferred.

11. *Payment of Excessive Stipends.* Paying excessive reimbursements for physician participation in SeronAIDS and SALSA, two purported studies run by Serono. The data collected through the studies was not used by Serono for any purpose, and no feedback was ever given to the physicians.

12. Through these activities and others, Serono and others knowingly caused consumers and third-party payors to pay for Serostim treatments that were not proven to be medically necessary (when they were provided at all), and that provided no medical benefit.

13. On October 17, 2005 the United States Attorney for the District of Massachusetts Michael J. Sullivan announced that after a four-year investigation, Serono would plead guilty to federal criminal charges and would pay restitution to settle civil charges for engaging in widespread fraudulent drug promotion and pervasive false and misleading marketing activities that caused medically unnecessary and unbeneficial prescriptions to be written and filled, resulting in false and fraudulent claims being submitted to and paid by governmental third-party payor Medicaid. A copy of the Felony Information filed against Serono Laboratories, Inc., 05 CR 10282 RCL (D. Mass. 10/17/05), incorporated herein in its entirety, is annexed hereto as Exhibit A. On December 15, 2005, Serono Laboratories did, in fact, plead guilty. A copy of the transcript of Plea and Sentencing of Serono Laboratories, Inc., incorporated herein in its entirety, is annexed hereto as Exhibit B. The plea agreement and associated settlement included the following elements:

14. *Guilty Plea to Criminal Conspiracy*. Serono Laboratories, Inc. would pleaded guilty to two counts of criminal conspiracy, to promote the use of adulterated medical devices with intent to defraud, and to offer and pay illegal remuneration. Serono Laboratories, Inc. would pay a criminal fine in the amount of $136.9 million. As a result of the criminal conviction, Serono Laboratories, Inc. also would be excluded from participating in any federal health care programs for a period of at least five years. A copy of the Plea Agreement, dated October 13, 2005, incorporated herein in its entirety, is annexed hereto as Exhibit C.

15. *Liability for All Serono Entities*. Although all criminal liability was attributed to Serono Laboratories, Inc., the United States Attorney stated that the evidence was sufficient to hold all Serono entities with civil liability. As was stated in the Government's Sentencing Memorandum:

> In addition to the criminal conduct, Serono Labs and its related Serono entities engaged in other conduct for which there may be insufficient evidence to establish criminal culpability but for which they have civil liability under the federal civil False Claims Act, 31 U.S.C. § 1329 *et seq.* and other civil statutes. . . . In evaluating the losses caused by the criminal conspiracies to which Serono Labs is pleading guilty, the United States Attorney's Office was cognizant of and examined the related civil liability to insure that the global criminal and civil settlement fully and fairly punishes Serono Labs for its criminal conduct, and fully and fairly compensates the affected federal and state health programs *for all of the Serono entities' conduct.*

(Emphasis added.) A copy of the Government's Sentencing Memorandum, Dated December 14, 2005, incorporated herein in its entirety, is annexed hereto as Exhibit D.

16. *Corporate Integrity Agreement.* Serono, Inc. and all other U.S. subsidiaries of Serono, S.A. would be subject to a stringent Corporate Integrity Agreement for five years. A copy of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Serono Holding, Inc., dated October 14, 2005, incorporated herein in its entirety, is annexed hereto as Exhibit E.

17. *Restitution to the United States.* Serono would pay $305 million, plus interest, to the United States in civil damages for losses suffered by the federal portion of the Medicaid program and other federal health care programs as a result of fraudulent drug promotion and marketing misconduct attributed for purposes of the plea bargain and settlement to Serono Laboratories, Inc.

18. *Restitution to the States*. Serono would pay a total of $262 million, plus interest, to settle its civil liabilities to the 50 states and the District of Columbia for losses suffered by the state Medicaid programs.

19. *Payment to be Made by Serono Entities.* In all, Serono was required to pay $704 million to state and federal officials in response to criminal and civil charges resulting from its illegal promotion of Serostim. Although all the improper conduct for purposes of the criminal plea and civil settlement was ascribed to Serono Laboratories, Inc., as admitted by Serono at the plea and sentencing hearing, the payment was funded by the Serono affiliated entities, including the parent company Serono International, S.A.

20. Agreement Not to Prosecute Serono, S.A., Serono Holding, Inc., Ares Trading, S.A., and Serono, Inc. As part of the criminal plea and settlement of civl charges, which included payment of fines and restitution by the Serono entities, the United States Attorney agreed not to prosecute the other Serono entities. A copy of the Side Letter Agreement between the United States Attorney and the Serono entities dated October 13, 2005, incorporated herein in its entirety, is annexed hereto as Exhibit F.

21. On March 30, 2005, RJL and its President, Rudolph J. Liedtke, were charged with criminal conspiracy for their roles in promoting the use of unapproved, adulterated and unproven medical devices and computer software marketed to fraudulently create a medical basis for prescription of Serostim. A copy of the Felony Information filed against RJL and Liedtke, 05 CR 10088 EFH (D. Mass. 3/30/05), incorporated herein in its entirety, is annexed hereto as Exhibit G. RJL and Liedtke pleaded guilty on April 19, 2005 and are awaiting sentencing. A copy of the transcript of Plea and Sentencing of RJL and Liedtke, incorporated herein in its entirety, is annexed hereto as Exhibit H.

22. In addition, on December 21, 2004, Adam Stupak, a Serono sales director, was charged and pleaded guilty to three counts of offering to pay illegal remuneration by offering doctors free trips to Cannes, France if they committed to write 30 prescriptions for Serostim in one week. A copy of the Felony Information filed against Stupack, 04 CR 10367 DPW (D. Mass. 12/21/04), incorporated herein in its entirety, is annexed hereto as Exhibit I. A copy of the transcript of Plea and Sentencing of Stupak, incorporated herein in its entirety, is annexed hereto as Exhibit J.

23. In addition, on April 15, 2005, four former executives of Serono were indicted on charges of offering bribes to doctors to prescribe Serostim. The indictments included charges of criminal conspiracy. The four people named in the indictment were John Bruens, marketing vice president; Mary Stewart, vice president of sales; Melissa Vaughn, regional sales director; and Marc Sirockman, regional sales director. A copy of the Indictment filed against Bruens, Stewart, Vaughn, and Sirockman, 05 CR 10102JLT (D. Mass. 4/14/05) incorporated herein in its entirety, is annexed hereto as Exhibit K.

24. In announcing the criminal pleas and civil settlement by Serono, United States Attorney Sullivan stated that *nearly 85 percent of prescriptions written for Serostim were not medically necessary*. In the Government's Sentencing Memorandum dated December 14, 2005, describing the conduct engaged in by Serono, the Government stated further:

> In sum, Serono Labs caused third-party payors, including Medicaid, to reimburse for prescriptions that would not have been written and/or for which third-party payors would not have paid. The evidence indicates that of all prescriptions written, approximately 85% of those were unnecessary for the patients for whom they were prescribed.

United States Attorney Sullivan also stated in announcing the criminal pleas and civil settlement by Serono that the medical testing procedure concocted by defendants Serono, RJL and Liedtke was "almost voodoolike," and that he suspected that some of the patients may also have suffered side effects as a result of taking the AIDS drug.

25. Serono's unlawful marketing and kickback activities resulted not only in fraud on the federal and state governments, but also fraud on consumers and third-party payors who, as a result of Serostim prescriptions written by physicians in reliance on defendants' fraudulent statements and conduct, paid for Serostim where there was no medical need or benefit. In addition, as stated by the Unites States Attorney for the District of Massachusetts, these activities may also have resulted in personal injury to AIDS victims treated with Serostim.

26. The civil settlement addressed the economic harm caused by defendants to governmental third-party payor Medicaid. But it did not address the harm caused to consumers and non-governmental third-party payors. At the plea and sentencing of Serono, Judge Reginald C. Lindsay spoke to this omission (Ex. B at 28-29):

> I have in mind the scenario where there are . . . especially vulnerable victims who are people who have AIDS; and as I understand what has happened, what the government charges and what the corporation is planning to plead guilty to, is the selling of devices and medication to these victims with the promotion by the corporation that a symptom of their illness was wasting of the body; and that even in cases where they may not have had that symptom, they were led to believe that they did have that indication, that they were suffering, and they paid for the medication, they paid for the devices, which means to me that the person who pays . . . his or her co-insurance . . can't [pay for] something else, other medication or pay the rent, pay the mortgage because it's going into the payment of -- for this device and this medication, which the patient had been led to believe is necessary for his health when it was not.

The Second Amended Class Action Complaint seeks to address the unjust enrichment to Serono and the economic harm suffered by consumers and non-governmental third-party payors, including plaintiffs.

27. As a result of its misconduct, Serono was also subject to multiple qui tam complaints each of which further articulates these and additional allegations of wrongdoing, as follows:

- *United States of America ex rel. Christine Driscoll v. Serono, Inc., Serono Laboratories, Inc. Ares-Serono, S.A., and Serono, S.A.*, C.A. No. 00-1680 (GAO) (D. Mass). A copy of the *Driscoll* complaint, incorporated herein in its entirety, is annexed hereto as Exhibit L.
- *United States of America ex rel. Sandra Boucher v. Serono Laboratories, Inc. and Serono, Inc.*, filed September 21, 2000 (D. Md.). A copy of the *Boucher* complaint, incorporated herin in its entirety, is annexed hereto as Exhibit M.
- *United States of America ex rel. AIDS Healthcare Foundation v. Serono, Inc. and Does 1 to 50,* CV04-0216 ABC (N.D. Ca.). A copy of the *AHF* complaint, incorporated herein in its entirety, is annexed herein as Exhibit N.

28. Ultimately, the United States intervened in these actions and a settlement agreement was entered into between the United States and Serono. A copy of the settlement agreement, incorporated herein in its entirety is annexed hereto as Exhibit O.

29. Serono also engaged in improper conduct with respect to the promotion of its other drug products. Defendants employed fraudulent, deceptive, and improper sales and marketing tactics to increase the sales of Serono's drugs and to reap unlawful profits at the expense of consumers and third-party payors. The improper sales and marketing practices

were based on Serono's providing financial assistance, including unrestricted educational grants, stipends, travel benefits, and other unlawful remuneration, to providers including physicians, physician groups, and hospitals, to increase Serono product sales and market share by causing physicians to prescribe Serono products instead of competing products or less expensive therapies. Serono's decisions to provide the grants and other inducements were accompanied by internal analysis concerning the "ROI," or "Return on Investment," that could be expected from the payment of the inducement. Serono actively concealed and caused others to conceal the inducements themselves, as well all terms upon which the inducements were given to providers, and its motivation and analysis in giving the financial assistance and other inducements to providers. The Second Amended Class Action Complaint seeks to address the economic harm suffered as a result of Serono's deception by consumers and non-governmental third-party payors, including plaintiffs, and the unjust enrichment to Serono.

30. Count I alleges a violation of the Racketeering Influence and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961(c). Serono associated itself systematically by contract and otherwise with a discrete and identifiable medical device marketing firm RJL and its principal Liedtke (hereinafter the "Serostim Medical Device Enterprise"), and others unknown, in order to form a RICO association-in-fact. The defendants controlled the enterprise. Through the use of this enterprise, defendants engaged in a pattern of racketeering activity that included promoting, distributing, and using adulterated, unapproved, and unproven medical devices and software throughout the country, and at least multiple episodes of mail fraud and wire fraud, for the purpose of conducting fraudulent body cell mass wasting tests and manipulating or fabricating the results of those tests, in order to cause physicians to prescribe Serostim without medical need or medical benefit. Consumers and third-party

payors were injured in their property by reason of these violations by, among other things, having to pay hundreds of million of dollars they would otherwise not have paid for Serostim by reason of the unlawful conduct Defendants knew that the objective of the enterprise was illegal and fraudulent. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

31. Count II also alleges a violation of the Racketeering Influence and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961(c). Serono associated itself systematically by contract and otherwise with discrete and identifiable sales consultants and 13 physicians (hereinafter the "Serostim Physician Kickback Enterprises"), and others unknown, in order to form RICO associations-in-fact. Through the use of these enterprises Serono engaged in a pattern of racketeering activity that included offering and paying illegal remuneration to specified individual physicians and at least multiple episodes of wire fraud. Each of the Physician Kickback Enterprises was formed and noted for the purpose of causing excessive and medically unnecessary Serostim prescriptions to be written, resulting in payment by consumers and third-party payors for prescriptions of Serostim that were neither medically necessary nor beneficial to patients. Consumers and third-party payors were injured in their property by reason of these violations by, among other things, having unnecessarily to pay millions of dollars for Serostim they would not have otherwise paid by reason of the unlawful conduct without medical need or medical benefit. Serono, the sales consultants, and each physician knew or had reason to know that the payment and acceptance of remuneration in order to promote the prescription of Serostim and support payment for the prescriptions by consumers and third-party payors was illegal and fraudulent. Serono controlled each of the Physicians Kickback Enterprises by making payments to each physician in exchange for each

physicians agreement to prescribe Serostim. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

32. Count III alleges a conspiracy in violation of RICO under 18 U.S.C. § 1962(d). Serono and its co-conspirators knowingly formed the enterprises identified above and knowingly engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, and by reason of this conduct consumers and third-party payors were injured in their property by, among other things, having unnecessarily to pay millions of dollars for Serostim by reason of the unlawful conduct without medical need or medical benefit. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

33. Count IV alleges a civil conspiracy. The defendants and others consciously and deliberately pursued a common plan to promote, distribute, and use adulterated, unapproved, and unproven medical devices and software for the purpose of conducting fraudulent body cell mass wasting tests in order to cause physicians to prescribe Serostim without medical need or medical benefit, and to provide illegal financial incentives to physicians for the purpose of causing excessive and medically unnecessary prescriptions to be written for Serostim. Consumers and third-party payors justifiably relied on the conspirators' false representations, concealments and nondisclosures, causing them to pay millions of dollars for Serostim they would not otherwise have paid without medical need or medical benefit. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

34. Count V alleges violation of the Massachusetts Consumer Protection Act, Chapter 93A. Defendants engaged in willful and knowing unfair and deceptive conduct in

connection with the promotion and sales of Serono products. Their wrongful acts occurred primarily and substantially in Massachusetts. As a proximate result of defendants' conduct, consumers and third-party payors paid unnecessarily for prescriptions of Serono products, thus suffering an injury within the meaning of Chapter 93A. The losses suffered by consumers and third-party payors were a foreseeable consequence of defendants' conduct. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

35. Count VI alleges a violation of other state consumer protection laws. As a direct result of Serono's willful and knowing deceptive, unfair, unconscionable, and fraudulent conduct, consumers and third-party payors paid unnecessarily for prescriptions of Serono products, thus suffering a loss within the meaning of applicable and consumer protection statutes. The losses suffered by consumers and third-party payors were a foreseeable consequence of defendants' conduct. Plaintiffs seek certification of a nationwide class or groups of classes and applicable damages on behalf of that class or classes.

36. Count VII alleges common law fraud. Defendants knowingly and willfully used and caused to be used unapproved and unproven medical devices and software, conducted fraudulent and misleading tests, and manipulated and fabricated test results, in order to generate data which would induce physicians to prescribe Serostim in circumstances where it was neither medically necessary nor beneficial. Consumers and third-party payors relied on the fraudulent tests and the prescriptions believing the Serostim prescriptions were medically necessary and beneficial in paying for Serostim, and were injured as a result. Defendants also knowingly and willfully paid illegal remuneration to physicians to prescribe Serono drug products, and concealed those payments from consumers and third-party payors, resulting in payments by consumers and third-party payors for Serono products that would

otherwise have not been made. Plaintiffs seek certification of a nationwide class or groups of classes and applicable damages on behalf of that class or classes.

37. Count VIII seeks relief in the nature of unjust enrichment. As a result of the concealed and unjustified travel stipends, financial assistance, unrestricted educational grants, and other unlawful remuneration paid by Serono to physicians who prescribed Serono drug products, Serono caused excessive and medically unnecessary prescriptions to be written for Serostim and other Serono products, resulting in unnecessary payments by consumers and third-party payors. Defendants have voluntarily accepted and retained the benefit of these payments with full knowledge and awareness that, as a result of their wrongdoing, plaintiffs paid for Serostim and other Serono products when they otherwise would not have done so. The failure of defendants to provide plaintiffs and the Class with the remuneration they expected enriched defendants unjustly. Serono benefited at the expense of the consumers and third-party payors in the United States. Plaintiffs seek certification of a nationwide class or groups of classes and applicable relief on behalf of that class or classes.

38. Finally, pursuant to Fed. R. Civ. P. 38, the Second Amended Class Action Complaint seeks a jury trial on all issues so triable.

II. PARTIES

39. Plaintiff Government Employees Hospital Association ("GEHA") is the third-largest national health insurance plan serving federal employees and retirees, as well as their families. GEHA has over 232,000 health plan members and provides health insurance to over 425,000 people across the United States and around the world. GEHA is a self-insured and not-for-profit association. As a third-party payor, GEHA paid for prescriptions of pharmaceutical products manufactured and marketed by Serono. GEHA is incorporated in the

state of Missouri and its corporate offices are located at 310 N.E. Mulberry, Lee's Summit, Missouri 64056.

40. District Council 37, AFSCME, AFL-CIO is a public sector union that represents 115,000 active employees of New York City and related agencies and authorities. The District Council 37 Health & Security Plan Trust ("DC 37 Plan") provides supplemental benefits, including a prescription drug benefit to DC 37's active and retiree population, covering approximately 350,000 lives. As a third party-payor, the DC 37 Plan paid for prescriptions of pharmaceutical products manufactured and marketed by Serono. The DC 37 Plan is located at 125 Barclay Street, New York, NY 10007.

41. Defendant Serono International, S.A. is a Swiss global biotechnology company with over 4,500 employees, and worldwide revenues in 2001 of $1.38 billion. Serono International, S.A.'s registered office is located at Centre Industrial in 1267 Coinsins/VD, and its executive offices are located at 15bis, chernin des Mines, Case Postale 54, CH-1211 Geneva 20, Switzerland.

42. Serono Laboratories, Inc. is a U.S. subsidiary of Serono International, S.A., organized under the laws of Massachusetts and both located and headquartered at One Technology Place, Rockland, Massachusetts, 02370.

43. Defendant Serono, Inc. is a U.S. subsidiary of Serono International, S.A., organized under the laws of Massachusetts and both located and headquartered at One Technology Place, Rockland, Massachusetts, 02370.

44. At all times material hereto, Serono acted by and through its duly authorized agents, employees, and representatives who were acting within the course and

scope of their agency, employment and representation, all of whom were acting at the direction of or with the consent, permission and authorization of Serono.

45. At all times material hereto, whenever this class action complaint refers to any acts of Serono, the reference shall be deemed to mean that of the directors, officers, employees, or agents of Serono authorized such acts while actively engaging in the management, direction, or control of the affairs of Serono, and while acting within the scope of their agency or employment.

46. RJL Systems, Inc., later known as RJL Sciences, Inc., is a corporation located in Clinton Township, Michigan, in the business of developing and marketing bioelectrical resistance and reactance measurement devices and associated computer software.

47. Rudolph J. Liedtke was the president and principal owner of RJL Systems, Inc.

III. JURISDICTION

48. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and pursuant to 28 U.S.C. § 1964(c), because this action alleges violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

49. Plaintiffs also invoke jurisdiction pursuant to 28 U.S.C. § 1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interests and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a state different from any defendant."

50. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 (b) and (c), and 18 U.S.C. § 1965(a), because one or more defendants transact business, are found,

or have agents in this District, and because a substantial portion of part or all of the alleged improper conduct took place in this District. Serono, through its maintenance of its principal place of business for its U.S. operations in this District and Serono, RJL and Liedtke, through their marketing and sales of Serostim and related medical devices and software, have transacted substantial business in this District.

IV. FACTS

A. Introduction of Serostim

51. Serono marketed and sold the drug Serostim, which is the proprietary name or trademark of the generic drug, "somatropin." Somatropin is recombinant human growth hormone, consisting generally of growth hormone taken from a mammalian cell line and modified, using recombinant DNA technology, by adding the human growth hormone gene.

52. Serono received accelerated approval from the FDA in August of 1996 for Serostim to treat AIDS wasting, also know as cachexia, a condition involving profound involuntary weight loss in AIDS patients, with a preferential loss of lean body mass over fat mass. At the time that the FDA approved Serostim, AIDS wasting was an AIDS defining condition that constituted the leading cause of death among AIDS patients.

53. Serostim was an injectable drug that was prescribed on a per milligram basis and was dispensed in vials. The dose most commonly administered was 6mg per day. In August 1996, the FDA approved Serostim based upon a 12-week course of treatment, although many patients received Serostim for more than 12 weeks.

54. Serostim was a very expensive drug. Serono set the average wholesale price ("AWP") for Serostim at $42 per mg. At 6mg per day, a 12-week course of Serostim therapy cost approximately $21,168.

55. Serostim came on the market concurrently with the advent of protease inhibitor drugs. These drugs, often referred to as Highly Active Anti-Retroviral Therapy, or HAART, dramatically curtailed, in the United States, the proliferation of the AIDS virus itself, particularly when used in combination with one another (commonly referred to as the "AIDS cocktail"). Given the decreased viral loads in HIV-positive patients taking these drugs, the incidence and prevalence of the AIDS wasting syndrome began to markedly decline among AIDS patients. Consequently, the medical necessity for Serostim began to diminish following the drug's launch. Serono knew or had reason to believe that decline in commercial demand for the drug would follow.

B. Serono's Campaign to Redefine AIDS Wasting

56. Commencing in 1997, and continuing thereafter, in order to salvage what it had expected to be a highly profitable market, Serono launched a campaign to "redefine AIDS wasting." Serono's goal was to create a market for Serostim by expanding the disease state for which Serostim could be prescribed as a treatment. Serono trained its sales force to make sales presentations and disseminate literature stating wasting was being "masked" by weight gain in the post-HAART era and that patients were still experiencing AIDS wasting following the advent of HAART, despite an absence of weight loss.

57. Serono also trained its sales and marketing employees to represent to physicians, patients, and others that "body cell mass" ("BCM") was the most metabolically active component of the body and that patients who had lost BCM were wasting, even if they had lost no weight or had actually gained weight. Serono represented that estimates of body cell mass in humans could be made by using bioelectrical impedance analysis ("BIA") medical devices in conjunction with certain software devices that purported to compute estimates of body cell mass. To "unmask" AIDS wasting, Serono, in concert with RJL,

promoted the use of the BIA and accompanying computer software devices to measure body cell mass.

58. During the clinical trials performed to obtain FDA approval for Serostim, the safety, efficacy, and necessity of Serostim were evaluated in test subjects who were diagnosed as suffering from AIDS wasting based upon changes in the amount of weight and lean body mass the subjects had experienced. Neither BCM testing nor BIA devices and associated software were ever used as a diagnostic tool to identify AIDS patients for whom Serostim therapy would be safe, effective, or necessary.

59. The BIA and software devices Serono used to promote sales of Serostim were developed and marketed by RJL Systems, Inc., later known as RJL Sciences, Inc. (hereinafter "RJL"), and Rudolph J. Liedtke (hereinafter "Liedtke"), the President and principal owner of RJL. These medical devices and software were never scientifically tested in conjunction with the diagnosis of AIDS wasting.

60. The BIA devices sold by RJL and Liedtke consisted of a portable device with two protruding electrodes to be attached to the hand and foot of human test subjects. Defendants represented that the BIA devices purported to measure the rate at which low levels of electrical current would pass through the body. A microchip embedded in the BIA device measured the degree to which the electrical current encountered "impedance" while passing through the body and calculated "resistance" and "reactance" measurements. The resistance and reactance measurements obtained by performing a BIA test reflected the degree to which the subject's body resisted the flow of the current and the extent to which the current was stored in the body.

61. Defendants represented that the resistance and reactance measurements generated by the BIA device were used to estimate the body composition of individual humans. Estimate of body composition were computed by applying the resistance and reactance measurements generated by the BIA device to predicative equations.

62. Defendants represented that predicative equations were developed by mathematically calculating the statistical relationship between the resistance and reactance measurements obtained and by performing BIA tests on a sample populations of human subjects and actual measurements of body compositions of humans varied depending on the characteristics and size of the sample population used to develop the equation and on the methodology used to measure the body composition within that population.

63. Defendant Serono purchased and distributed, and caused to be purchased and distributed by others, the BIA medical devices and associated software developed and marketed by RJL and Liedtke. Serono also promoted the BIA medical devices and associated software for the purpose – unapproved by the FDA and scientifically unproven – of identifying AIDS victims whose purported non-weight losing AIDS wasting symptoms should be treated with Serostim.

C. The Regulatory Framework for Approval of Medical Devices

64. The BIA device was a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(h), in that the BIA device was an impendence plethysmograph used to estimate human body composition by estimating "peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs" 21 C.F.R. § 870.2770.

65. Each package of computer software used to convert the resistance and reactance measurements generated by the BIA device into estimates of body composition was

also a medical device within the meaning of the FDCA in that it was a "component, part, or accessory" to BIA devices pursuant to 21 U.S.C. § 321(h).

66. The Center for Devices and Radiological Health ("CDRH") was the office within the FDA responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law.

67. The BIA and computer software devices could not be sold without first obtaining premarket clearance and premarket approval from the FDA, depending on the intended use of the devices. FDA could grant a 510(k) premarket clearance if it determined, following review of the data submitted in support of the applicant's premarket notification, that a device was substantially equivalent to a device (known as a "predicate device") that was marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Food, Drug and Cosmetics Act ("FDCA").

68. A device could only be found substantially equivalent to a predicate device if, among other things, the intended use of the current device was the same as the intended use of a predicate device. If the intended use of the device was different from the intended use of a predicate device, substantial equivalence could not be found. Under such circumstances, it was illegal for a manufacturer to market the device in interstate commerce unless the FDA had first reviewed and approved a premarket application to market the device.

69. FDA categorized devices into three classes – Class I, Class II, and Class III -- depending on the degree of regulation necessary to ensure the safety and effectiveness of the devices for their intended uses. Devices that were first introduced into commercial distribution after May 28, 1976, were presumed to be Class III devices by operation of law.

21 U.S.C. § 360c(f)(1). A Class III device, unless the subject of a 510(k) premarket clearance, required premarket approval before it could be legally marketed in interstate commerce. 21 U.S.C. § 360e. Premarket approval review by the FDA generally entailed, among other things, a review of clinical trials and scientific data offered to confirm the safety and efficacy of the device as well as a review of the device's labeling, which must include adequate directions for use.

70. On or about June 24, 1986, RJL and Liedtke submitted a 510(k) premarket notification to FDA's CDRH relating to a BIA device identified therein as "Body Comp Analyzer" and a computer software device accompanying the device. In that 510(k) submission and in ensuing correspondence with CDRH, RJL and Liedtke stated that the Body Comp Analyzer and accompanying computer software had the same intended uses as those identified in a 510(k) premarket notification that RJL had filed with CDRH in 1983 – specifically, estimating total body water, lean body mass, and fat – and that the computer software only performed calculations that previously would have been done by hand to estimate body composition. RJL and Liedtke further represented that the predictive equations in the computer software were based on a population consisting of 278 healthy and obese college students whose body composition was measured through hydrostatic weighing. RJL and Liedtke also stated that total body water measurements of the college students were determined using deuterium oxide dilution. RJL and Liedtke represented to CDRH that the intended uses of the BIA device and accompanying computer software did not include measuring body cell mass or diagnosing any disease state.

71. Based on the representations made by RJL and Liedtke in their 510(k) submission and related communications, CDRH concluded that the modified Body Comp

Analyzer and accompanying software were substantially equivalent to a device marketed prior to the medical device amendments of 1976. On February 3, 1987, CDRH granted premarket clearance to RJL to distribute the Body Comp Analyzer and the accompanying computer software devices, referred to by CDRH as the "Modified Model BIA-103 Body Comp Analyzer," for the intended uses of estimating total body water, lean body mass, and fat in healthy humans.

D. The Unapproved Development of Software Devices for Measuring Body Cell Mass

72. Serono, RJL, Liedtke, and others unknown developed various versions of software for the BIA medical device purported to calculate, among other things, body cell mass, total body water, fat free mass, and intracellular and extracellular water. The various software packages were named "Fluid and Nutrition Analysis," "Cyprus," "SomaScan," and "Cyprus 1.2 Condensed." Each of these software packages, pursuant to 21 U.S.C. § 351(f)(1)(B)(i), required FDA approval before they could be legally marketed for new and intended use of measuring body cell mass and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements. At no time did any individual or entity submit an application for premarket approval to the FDA with respect to any of these software packages, nor has FDA ever approved an application for premarket approval for any of the software packages under 21 U.S.C. § 360e.

1. The FNA Software

73. Commencing in at least 1994, RJL and Liedtke and others unknown developed a predicative equation that would purportedly calculate estimates of body cell mass using the BIA resistance and reactance readings. This predicative equation (herein after the "Z equation") purported to estimate body cell mass based upon measurements of total body

potassium in a population referred to herein as the "ABC database" that consisted of approximately 332 humans, including individuals who were healthy and others who had been tested as HIV-positive.

74. Commencing sometime during 1994, RJL and Liedtke, and others unknown, developed new computer software for use in interpreting BIA test results as a tool for diagnosing AIDS wasting. The software incorporated the Z equation. RJL and Liedtke marketed the software under the name "Fluid and Nutrition Analysis," ("FNA"). The FNA software purported to calculate an individual's estimated body cell mass, total body water, intracellular and extracellular water, fat free mass, extracellular tissue, and fat. The FNA software also computed purported "normal" ranges for the individual's total body water and intracellular and extracellular water by comparing the individual's BIA test results to that of a select portion of the population included in the purported ABC database. The inclusion of the Z equation and the database in the FNA software, and the use of the computer software to purportedly measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses that required premarket approval from FDA before their introduction into interstate commerce as a basis for diagnosing AIDS wasting and promotion of the administration of Serostim as treatment.

75. In or about January, 1995, RJL and Liedtke met with representatives of Serono and with others unknown concerning the use of BIA technology by Serono in the promotion of Serostim.

76. Between September 1995 and June 1996, RJL shipped approximately 25 BIA devices together with FNA Version 3.1 software packages to Serono for use by Serono in evaluating body composition in AIDS patients.

2. The Cyprus Software

77. The "Cyprus" software, developed for the BIA medical device commencing in or about 1998, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus software further computed purported normal ranges for each of these measurements for individuals by comparing the individual's test results to a select portion of database of humans derived from the National Health and Nutrition Examination Survey (NHANES).

3. The SomaScan Software

78. The "SomaScan" software, developed for the BIA device commencing in or about August, 1999, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The SomaScan software further computed purported precise "ideal" amounts for each of these measurements for individual test subjects by comparing the individual's test results to a select portion of the NHANES database and eliminating any standard deviation from the calculations. The SomaScan software was not submitted to FDA for premarket approval and was not approved by FDA for shipment in interstate commerce for the intended uses of measuring body cell mass or diagnosing AIDS wasting. The inclusion of the Z equation, employing the NHANES database as the population base for computing "ideal" body composition values in the SomaScan software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses, and required premarket approval from FDA before their introduction into interstate commerce and use as a basis for diagnosis of AIDS wasting and promotion of the administration of Serostim as treatment.

4. The Cyprus 1.2 Condensed Software

79. The "Cyprus 1.2 Condensed" software, developed for the BIA device in or about February, 2000, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus 1.2 Condensed software also computed purported "normal" amounts and "normal" ranges for these values for each individual by comparing the individual test subject's results to a select portion of the NHANES database and including a standard deviation for these calculations. The inclusion of the Z equation, employing the NHANES database as the population base for computing "normal" body composition values in the software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses, and required premarket approval from FDA before introduction into interstate commerce and use in the diagnosis of AIDS wasting and the promotion of administration of Serostim as treatment.

E. Defendants' Fraudulent Promotion of Serostim Through Use of the Unapproved and Unproven Medical Devices and Associated Software

77. Commencing as early as September, 1996, and continuing thereafter, Serono, RJL, Liedtke, and others unknown, knowingly and willfully agreed to introduce and deliver for introduction into interstate commerce, with intent to defraud and mislead, BIA computer software for use in diagnosing AIDS wasting based upon BIA resistance and reactance measurements, knowing that these devices had not been approved for use diagnosing AIDS wasting and were therefore adulterated medical devices within the meaning of 21 U.S.C. § 351(f)(1)(B)(i).

78. Despite knowing that the devices lacked FDA approval and were otherwise unproven, Serono, RJL, Liedtke, and others unknown promoted the use of BIA technology to physicians, patients, and third-party payors as an necessary device for determining whether Serostim should be prescribed and reimbursed. Serono, RJL, Liedtke, and others unknown knowingly engaged in an array of practices to fabricate and manipulate the BIA test and to deceive physicians, patients, consumers, and third-party payors regarding the test's reliability in diagnosing AIDS wasting. The purpose of this conspiracy was to illegally and fraudulently disseminate adulterated and unproven BIA devices to obtain millions of dollars in profits to which defendants were not entitled by causing unnecessary prescriptions o be written and consumers and third-party payors to pay for prescriptions of Serostim that were not medically necessary or beneficial.

79. Serono thus launched a campaign to "redefine AIDS wasting" in order to create a market for Serostim by fraudulently expanding the disease state for which Serostim could be prescribed as a treatment. The Serono sales force made sales presentations and disseminated literature stating that wasting was being "masked" by weight gain and that patients were still experiencing AIDS wasting following the advent of protease inhibitors, despite an absence of weight loss. Serono trained its sales and marketing employees to represent fraudulently to physicians, patients, and others that BCM was the most metabolically active component of the body and that patients who had lost BCM were wasting, even if they had lost no weight or had actually gained weight. The company taught its sales representatives fraudulently to advocate to physicians that estimates of BCM in humans could be made by using BIA machines with certain software devices that purported to compute estimates of BCM.

80. To "unmask" AIDS wasting, Serono, RJL, Liedtke, and others unknown promoted the use of adulterated BIA and accompanying computer software devices to measure BCM. The purpose of the conspiracy to promote the adulterated, unapproved, and unproven devices into interstate commerce was to obtain millions of dollars in payments from consumers and third-party payors for sales of Serostim by generating prescriptions for AIDS patients who did not need the drug because they were not actually wasting.

81. In engaging in this conduct, Serono, RJL, Liedtke, and others unknown formed the Medical Device Enterprise. Serono, RJL, Liedtke, and others unknown controlled the direction of the Medical Device Enterprise and knowingly used the Medical Device Enterprise to engage in fraudulent and unlawful conduct and to achieve unlawful objectives.

82. The purpose of the Medical Device Enterprise was to introduce and deliver into interstate commerce with intent to defraud and mislead unapproved, adulterated and unproven medical devices in order to create a false and fraudulent basis for physicians to write Serostim prescriptions where no medical necessity or benefit for the drug existed. The purpose of the Medical Device Enterprise was also to create a market for sales of BIA devices and software to be used to conduct fraudulent BIA tests to create a basis for physicians to write Serostim prescriptions which were not needed or beneficial. The promotion of the adulterated, unapproved, unproven BIA devices by the Medical Device Enterprise caused prescriptions to be written for Serostim that had no medical necessity and caused consumers and third-party payors to pay for Serostim treatments that provided the patients with no medical benefit.

80. Serono, RJL, Liedtke, and others unknown, knowingly participated in the development and dissemination of fraudulent BIA computer software that purported to measure body cell mass for use in diagnosing AIDS wasting based upon a test subject's

purported loss of body cell mass. The disease state of AIDS wasting, however, as defendants knew or should have known, consisted of profound involuntary weight loss and loss of lean body mass in AIDS patients, not loss of body cell mass. Use of BIA devices and computer software that purported to measure loss of body cell mass enabled Serono and others unknown, including RJL and Liedtke, to "redefine" AIDS wasting market for Serostim beyond the disease state for which the drug was approved and scientifically proven to be necessary, and caused consumers and third-party payors to pay for Serostim therapy that was medically unnecessary, not beneficial, and potentially unsafe. It also provided a stimulus for increased sales of the BIA devices and associated software.

81. As part of the Medical Device Enterprise, Serono also disseminated BIA devices and related software in interstate commerce to its sales representatives to promote sales of Serostim based on purported loss of body cell mass, even without evidence of weight loss. This was done without first obtaining FDA approval for this use of the device with the FNA software, or without proving its validity.

82. Serono, RJL, and Liedtke also developed and disseminated the "SomaScan" software in interstate commerce to sales representatives of Serono and to others unknown in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "ideal" levels of body cell mass and other body composition parameters for individual BIA test subjects, all without first obtaining FDA approval for these uses of the device with the SomaScan software or proving its medical effectiveness or necessity. In doing so, Defendants and the Medical Device Enterprise sought to create a purported basis for the prescribing and sale of Serostim for medically unnecessary purposes and increase the prescribing and sale of Serostim, allowing defendants to obtain

payments from consumers and third party payors for pharmaceutical products that conferred no benefit on patients..

83. Serono, RJL, and Liedtke also developed and disseminated the "Cyprus 1.2 Condensed" software in interstate commerce to sales representatives of Serono and to others unknown in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "normal" levels of body cell mass and other body composition parameters, all without first obtaining FDA approval for these uses of the device with the Cyprus 1.2 Condensed software or proving its medical effectiveness or necessity. In so doing, Defendants and the Medical Device Enterprise sought to increase the market potential for Serostim and to create a purported basis for prescribing and sale of Serostim for medically unnecessary purposes.

84. Serono, RJL, and Liedtke also sought to provide a basis for Serono and others unknown to induce physicians to prescribe, and third-party payors to pay for, Serostim based upon misrepresentations and omissions of material facts. Serono misled physicians and third-party payors regarding the validity of BIA testing in diagnosing AIDS wasting and did not disclose that BIA software devices had not been approved by FDA or scientifically validated for the purposes of determining whether patients were experiencing purported changes in body cell mass or suffering from AIDS wasting.

85. Defendants and their sales representatives also fraudulently encouraged physicians to prescribe Serostim in quantities that their patients did not need or could not consume, and had procured from physicians signed prescriptions forms which they used to submit additional unneeded Serostim prescriptions.

86. As a consequence of these material misrepresentations and omissions, Defendants individually and through their control of the Medical Device Enterprise knowingly caused consumers and third-party payors to reimburse for Serostim prescriptions that were not medically necessary or beneficial would not have been written and for which the consumers and third-party payors would decline to have paid.

F. Defendants' Agreements and Actions to Implement Use of the Unapproved and Unproven Medical Devices to Support Fraudulent Bases for Serostim Prescriptions and Expenditures by Consumers and Third-Party Payors

87. Beginning in 1996, Serono, RJL, Liedtke, and others unknown, embarked on a campaign to improperly promote and market BIA and associated computer software in order to fraudulently increase the number of Serostim prescriptions written and paid for by consumers and third-party payors. Among other things, the Defendants and others unknown, distributed BIA medical devices and associated software to Serono's sales representative, and trained and supervised them in the presentation of these devices to purportedly measure body cell mass, diagnose AIDS wasting, and promote the sale of Serostim.

88. In or about September 1996, a representative of Serono traveled to Clinton Township, Michigan, and met with RJL, Liedtke, and others unknown regarding possible uses of the BIA and FNA software devices by Serono in marketing Serostim.

89. In or about October 1996, representatives of Serono met with Liedtke and employees of RJL and others unknown in Massachusetts regarding the sale and delivery of BIA and FNA software devices by RJL to Serono and others unknown.

90. In or about December 1996, Serono received in Massachusetts approximately 50 BIA devices, accompanied by approximately 50 FNA software devices that included the Z equation, manufactured by RJL and Liedtke and shipped from Michigan.

Pursuant to directions and specifications from Serono, RJL and Liedtke affixed plates to the outside of these BIA devices bearing name "Serono."

91. Commencing in or about February 1997, and continuing thereafter, Serono provided the BIA devices and FNA software received from RJL and Liedtke to Serono's sales representatives and to others unknown for use in measuring body cell mass, diagnosing AIDS wasting in human who were potential candidates for receiving the drug, and promoting sales of Serostim.

92. Commencing in or about March 1997, and continuing thereafter, employees of RJL traveled from Michigan to Massachusetts and elsewhere, at Serono's request, and provided training to Serono's sales representative in performing BIA tests on humans.

93. Commencing in 1997, and continuing thereafter, Serono's representatives performed, free of charge, BIA tests directly on AIDS patients in physician and medical clinic offices and at events sponsored by service organizations offering assistance to AIDS patients. Serono's sales representatives provided the BIA test results to doctors and patients and, in many instances, purported to interpret the test results for the purpose of diagnosing whether the patients were wasting and determining whether they needed Serostim.

94. In some cases, Serono sales representatives actually manipulated the BIA test results for individual patients to support prescriptions under the false and fraudulent criteria that Serono was promoting. In other cases, the tests were given on patients who had not properly fasted prior to administration of the test, rendering the results meaningless; nevertheless, Serono advocated using these test results as the bases for prescriptions. The intended consequence of this conduct was to cause consumers and third-party payors to pay or

reimburse for Serostim prescriptions that would not have been written or paid for in the absence of the fraudulent conduct by the defendants.

95. Commencing in or about June 1997, and continuing thereafter, Serono forwarded to its sales representatives copies of various training materials prepared by RJL and by others for the purpose of training Serono sales representatives in performing BIA tests on humans and in interpreting BIA test results.

96. In or about June 1997, Serono obtained from RJL a "Body Composition Analysis Worksheet" and disseminated it to Serono's representatives for use in interpreting BIA tests and obtaining reimbursement for Serostim from third-party payors.

97. Commencing in 1999, and continuing thereafter, Serono required its sales representatives to submit bi-weekly reports to Serono's management showing how many BIA tests the sales representatives performed and how many prescriptions of Serostim were obtained as a result of those BIA tests.

98. Thereafter, Serono provided, free of charge, BIA medical devices and software devices to physicians and others involved in treating AIDS patients, and further arranged for the purchase, by physicians and others, of BIA and software devices at a reduced cost. Serono also provided training in performing and interpreting BIA tests to physicians and others involved in treating AIDS patients, and arranged for such training to be provided by others.

99. Commencing in 1996, and continuing thereafter, Serono, RJL, and Liedtke promoted reliance upon BIA test results by third-party payors, for the purpose of determining whether a patient was suffering from AIDS wasting and whether to reimburse for Serostim prescriptions.

100. In or about August 1997, Serono executed a written agreement governing the sale of by RJL and Liedtke of BIA and computer software devices. Pursuant to this agreement, Serono and RJL agreed that RJL would provide "a specialized, private labeled model [BIA device] for Serono" that included, among other things," "R.J.L.'s Fluid & Nutrition Analysis Clinical Software Program for medical reimbursement," and further agreed to cooperate with RJL "for the development of new software and/or hardware for the diagnosis and monitoring of AIDS Associated Wasting and monitoring treatment with Serostim."

101. Commencing in or about August 1999, Serono collaborated with RJL and Liedtke and others unknown in the creation of the BIA computer software package known as "SomaScan." Serono knew and intended that the SomaScan software computed "ideal" body composition values by comparing the individual subject's BIA test results to a select portion of a database of humans derived form the NHANES database, and that the SomaScan software provided these "ideal" values as precise numerical amounts, rather than as ranges for these values. Serono expressly directed RJL and Liedtke to eliminate any standard deviation from the SomScan software in order to identify additional purported candidates for receiving Serostim and to increase sales of Serostim.

102. Commencing in or about August 1999, Serono received various versions of the SomaScan software from RJL, created copies of the computer software, and affixed labels to this software that identified it as SomaScan software and bore the name "Serono."

103. Commencing in or about September 1999, Serono disseminated the SomaScan software to its sales representatives and to others unknown to the United States Attorney for use in measuring body cell mass, diagnosing AIDS wasting in humans who were potential candidates for receiving Serostim, and promoting sales of Serostim.

104. Commencing in or about September 1999, Serono prepared and disseminated training materials regarding the SomaScan software, provided training to sales representatives and to other unknown in the use of the software, and established a "Hotline" that users of the SomaScan software could telephone to obtain guidance in using the software.

105. Commencing in or about September 1999, RJL and Liedtke, acting at the direction of Serono, prepared and posted a website which provided information and training regarding the use of the SomaScan software.

106. Commencing in or about October 1999, and continuing thereafter, Serono initiated an assessment of the validity of the SomaScan software after receiving complaints that the SomaScan software was flawed and that BIA tests performed using the SomaScan software showed individuals to have AIDS wasting who were not in fact wasting.

107. Commencing in or about February 2000, Serono, RJL, Liedtke, and others unknown, evaluated the possible use by Serono of version of RJL computer software known as Cyprus. Pursuant to directions from Serono, RJL and Liedtke created the version of the Cyprus software known as Cyprus 1.2 Condensed for use by physicians and others unknown.

108. In or about September 2000, Serono decided to withdraw the SomaScan software from use by its representatives. In place of the SomaScan software, Serono disseminated the Cyprus 1.2 Condensed software to Serono sales representatives and others unknown for use in purportedly measuring body cell mass, diagnosing AIDS wasting in humans, and promoting sales of Serostim.

109. Commencing in or about September 2000, and continuing until at least January 2002, Serono disseminated the Cyprus 1.2 Condensed BIA software to others unknown for use in purportedly measuring body cell mass and diagnosing AIDS wasting in

humans who were potential candidates for receiving the drug, and promoting sales of Serostim.

110. Defendant's campaign of criminal fraud and deceit resulted in windfall revenues for Serono. Serono, S.A. announced in a January 18, 2000 news release that "Serostim further expanded its leadership in the treatment of AIDS wasting in the U.S. market, with sales rising 55.9% to $137.4 million from 88.2 million in 1998." What defendant did not disclose was that these revenues resulted from a course of deceptive and illegal conduct knowingly and willfully undertaken by Serono and others that resulted in millions of dollars of prescriptions of Serostim that were paid for by consumers and third-party payors without medical necessity or scientifically valid proven effectiveness or benefit.

G. Defendants' Plan to Fraudulently Promote Serostim Through Payment of Kickbacks to Specific Physicians and to Cause Consumers and Third-Party Payors to Pay for Unnecessary Prescriptions

111. From in or about 1996 through in or about September 2000, Serono's Metabolic and Immune Therapy business unit (hereinafter "M&IT") was responsible for marketing and selling Serostim in the United States. Following a corporate reorganization in or about September 2000, the business unit responsible for selling Serostim in the United States was known as "Metabolic Endocrinology of North America" ("MENA").

112. In March 1999, the M&IT sales force was divided into six sales Regions each led by a Regional Director: the Northeast Region (Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State); the New York Region (New York City and its environs); the Southeast Region (Florida, Louisiana, Mississippi, Alabama and Texas); the Central Region (Illinois, Wisconsin, Missouri, Arkansas, Oklahoma, Kentucky, Michigan, Minnesota, North Dakota, South Dakota, Nebraska, Iowa and Indiana); the Mid-Atlantic Region (Maryland, Delaware, Georgia, North Carolina, South Carolina,

Ohio, West Virginia, and part of Pennsylvania); and the Western Region (California, Oregon, Washington, Arizona, and Colorado).

113. John Bruens (hereinafter referred to as "Bruens") held various positions in Serono. In 1999, defendant Bruens was the Vice-President of Marketing for M&IT working out of Serono headquarters in Massachusetts and reported directly to Executive X.

114. Mary Stewart (hereinafter referred to as "Stewart") held various positions in Serono. In 1999, Stewart was the Vice-President of Sales of M&IT working out of Serono headquarters in Massachusetts and reported directly to Executive X.

115. Melissa Vaughn (hereinafter referred to as "Vaughn") held various positions in Serono's M&IT business unit. In 1999, Vaughn was the Regional Director of Sales for the Southeast Region and reported directly to Stewart. As Regional Director of Sales for the Southeast Region, Vaughn supervised sales representatives (known within Serono as "clinical consultants") in Florida, Louisiana, Mississippi, Alabama and Texas.

116. Marc Sirockman (hereinafter referred to as "Sirockman") was employed by Serono's M&IT business unit in a variety of positions. In or about January 1999, Sirockman became Regional Director for the Northeast Region and reported directly to defendant Stewart. As Regional Director of Sales for the Northeast Region, Sirockman supervised clinical consultants in Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State.

117. At various times, Bruens, Stewart, Vaughn and Sirockman, along with others both known and unknown, including Adam Stupak, who was the Regional Director of Sales for the New York Region, were among top management responsible for sales and marketing of Serostim.

118. Prior to filing its two-count Information against Serono Laboratories, Inc., the United States Attorney for the District of Massachusetts filed indictments against Bruens, Stewart, Vaughn and Sirockman in the Untied States District Court, District of Massachusetts.

119. The United States Attorney also filed a three-count Information against Stupak, to which Stupak has pleaded guilty.

120. In the indictment, Drs. FL, P, DC, AC, O, G and W are each identified as physicians who provided care and treatment for patients who were HIV positive or suffering from AIDS. Drs. RL and P are identified in the indictment as located in and treated patients in Florida; Drs. CD and AC were located in and treated patients in New Jersey; and Drs. O, G and W were located in and treated patients in New York. Each of these physicians prescribed Serostim from time to time to patients.

121. During 1999, the top managers of Serono's M&IT business unit who were responsible for Serostim sales and marketing were Executive X and Bruens and Stewart.

122. In or about late 1998 or early 1999, Serono scheduled a National Sales Meeting to be held in Massachusetts from March 15-19, 1999, at which time representatives from various corporate business units of Serono, and Bruens and Stewart on behalf of the M&IT unit, would be required to present sales information concerning the products being marketed by their respective corporate business units.

123. In February 1999, Bruens and Stewart were aware that the M&IT business unit was falling significantly short of its sales goals with respect to sales of Serostim.

124. The 3rd International Conference on Nutrition and HIV Infection was to be held in Cannes, France from April 22-25, 1999 (hereinafter referred to as the "Cannes Conference"). The Cannes Conference was organized to include new data on advances in the

treatment of nutritional aspects of HIV disease, including but not limited to the effects of protease inhibitors on body composition, metabolism and hormone systems.

H. Defendants' Implementation of the Plan To Pay Specific Physicians Inducements in Exchange for Writing Serostim Prescriptions

125. Commencing on or about March 1, 1999, and continuing thereafter until in or about December 1999, Serono, along with Bruens, Stewart, Vaughn, Sirockman, Executive X, Stupak, and others unknown, knowingly and willfully combined, conspired, and agreed to offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to specific, identified physicians to induce each of them to refer individuals to pharmacies for the furnishing of the drug Serostim. The association of Serono, the Serono managers, and each specified physician, are known collectively as the Physician Kickback Enterprises.

126. The purpose of the Physician Kickback Enterprises was to pay physicians who were high prescribers of Serostim or who were generally regarded as "thought leaders" financial incentives in order to obtain the number of prescriptions that would advance a sales goal of increasing sales of Serostim by $6,000,000, which was to be accomplished by offering an all-expenses paid trip to each physician and a guest to the Cannes Conference in return each of the physicians writing additional prescriptions of Serostim.

127. To advance the purposes of the Physicians Kickback Enterprises, Executive X and Bruens and Stewart devised a plan called the "$6m-6 Day Plan," which had as an objective to make illegal payments to each physician to write more prescriptions -- specifically, an all-expenses paid trip to the Cannes Conference for the physician and a guest.

128. Pursuant to that plan, Bruens and Stewart summoned the six Regional Directors of M&IT, including Stupak, Vaughn, and Sirockman, to an emergency meeting at the Boston Harbor Hotel in Massachusetts on March 1, 1999. At this meeting, which included

other M&IT personnel, Executive X, Bruens, and Stewart told the six Regional Directors that they were falling short of their sales goals for Serostim. Executive X, Bruens and Stewart also advised the Regional Directors that they needed to "dig their way out" of this fiscal crisis and informed the Regional Directors of the "$6m-6 Day Plan."

129. Stewart and Bruens told the Regional Directors to get their prescribers to write prescriptions. Stewart coined the term the "$6m-6 Day Plan" in her follow-up e-mail. In that e-mail, Stewart spelled out exactly what Regional Directors were to do, including instructing them what they were to tell their clinical consultants to do, *i.e.*, identifying which doctors they were to target, requiring that the clinical consultants report their results (new scripts) daily, and zeroing in on doctors who could give Serono results -- meaning new prescriptions. Stewart also instructed another employee of Serono to create a special spread sheet for this reporting, which was used by the Regional Directors to report daily results until March 11, 1999. Stewart reminded everyone that this was to be a "team effort" so that they could "deliver [their] numbers," meaning sales.

130. Although this target number of prescriptions per physician changed over time, the "$6m-6 Day Plan," as originally explained by Bruens and Stewart, would increase total sales of Serostim by more than $6,000,000 within six days.

131. To implement the plan, Bruens and Stewart required each Regional Director, including Stupak,Vaughn, and Sirockman, to report daily to Serono headquarters in Massachusetts the number of Serostim prescriptions that they obtained during the sales push, including those prescriptions obtained from the physicians who were offered the Cannes Conference inducement. The Regional Directors made these reports and sent them to headquarters in Massachusetts.

132. The Regional Directors were expected to make the Cannes offers in early March of 1999 so that they could get the necessary prescriptions to increase sales. After the March 1 meeting in Boston, the Regional Directors implemented the program. Expense reports confirm meetings during the next few days with clinical consultants and doctors. One regional director reached out to his clinical consultants who assisted him in calling upon the "top prescribers" that he was targeting. Late in the evening of March 1, 1999, one physician received a voice mail from a Regional Director advising him that the company was targeting their top prescribers and would offer them a trip to the Cannes conference in return for their writing 30 scripts within 30 days. At least two doctors called the offer an "inducement," "inappropriate" and "wrong." Certain doctors were upset about the offer and refused to participate. One doctor referred to it as a "bribe."

133. Approximately 20 doctors were offered the trip and 13 accepted. Several doctors denied a connection between the trip and an increase in prescriptions; several were upset by the proposition and so advised the sales representatives; some indicated acquiescence to the proposition but did not go; others agreed to go but did not go; still others agreed to go and did go. The Regional Directors and others telephoned and e-mailed the sales force passing forward the directions of the top management, including Bruens and Stewart, advising of the plan, and implementing the plan. John Bruens directed the plan; therefore his executive assistant was the contact person for the doctors and was responsible for issuing invitations to the doctors, coordinating travel, itineraries, and organizing the dinners at Cannes sponsored by Serono.

134. As a consequence of the plan, Serono offered and caused to be offered to selected physicians the opportunity to attend the Cannes Conference with a guest with all

expenses paid by Serono in return for the physicians writing additional prescriptions of Serostim.

135. As part of the implementation of the plan, in exchange for the physicians' writing additional Serostim prescriptions, Serono paid for the travel expenses of each of the physicians and their guests who attended the Cannes Conference.

136. In exchange for the physicians' Serostim's prescriptions, Serono paid thousands of dollars for the hotel accommodations, meals, and entertainment for each of the physicians and their guests while they were at the Cannes Conference.

137. Further, Serono authorized and caused a variety of personal gifts to be provided to each of the physicians and their guests who attended the Cannes Conference.

138. After certain physicians rejected the Cannes offer, Serono advised certain of the physicians who had already accepted the inducement that each of them would be asked to speak on behalf of Serono about the issues presented at the conference and about Serostim, and would be paid separately for these speaking engagements.

I. Defendants' Payment of Inducements to Specify Physicians to Prescribe Serostim

1. The Offer to Dr. RL

139. Between on or about March 1 and on or about March 3, 1999, a Serono clinical consultant visited Dr. RL, a physician in Florida who treated HIV positive and AIDS patients, and offered Dr. RL the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.

2. The Offer to Dr. P

140. Between on or March 1, 1999 and on or about March 3, 1999, a Serono clinical consultant visited the office of Dr. P, a physician in Florida who treated HIV positive

and AIDS patients, and offered Dr. P the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.

141. On or about March 13, 1999, defendant Vaughn advised Bruens that Dr. P would attend the Cannes Conference and would need business-class airline tickets.

142. On or about April 8, 1999, Bruens directed an employee in Norwell, Massachusetts, to charge $7,846.64 on a corporate credit card to cover the cost of Dr. P's round trip airfare, which had been booked by Serono's travel agency.

3. The Offer to Dr. DC

143. In or about March 1999, the exact dates being unknown, a Serono clinical consultant visited the office of Dr. DC, a physician in New Jersey who treated HIV positive and AIDS patients, and offered Dr. DC the all-expenses paid trip to the Cannes Conference in return for gaining clinical experience with at least 30 Serostim patients before Dr. DC could attend the conference.

4. The Offer to Dr. AC

144. In or about March 1999, the exact dates being unknown, Sirockman contact Dr. AC, a physician in New Jersey who treated HIV positive and AIDS patients, and offered him the all-expenses paid trip to the Cannes Conference in return for writing of additional prescriptions of Serostim.

145. On or about April 15, 1999, Serono caused Dr. AC to receive a check in the amount of $4,000 for airline tickets.

146. On or about April 25, 1999, Sirockman, using his corporate expense account, paid for Dr. AC's transportation in a private limo service for Dr. AC's return to his resident from an airport in New York after the Cannes Conference.

5. The Offer to Dr. O

147. Between on or about March 1, 1999 and on or about March 4, 1999, Adam Stupak visited the office of Dr. O, a physician in New York City who treated HIV positive and AIDS patients, and offered Dr. O the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

6. The Offer to Dr. G

148. Between on or about March 1, 1999 and on or about March 4, 1999, Adam Stupak visited the office of Dr. G, a physician in New York City who treated HIV positive and AIDS patients, and offered Dr. G the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

7. The Offer to Dr. W

149. Between on or about March 1, 1999 and on or about March 4, 1999, Adam Stupak visited the office of Dr. W, a physician in New York City who treated HIV positive and AIDS patients, and offered Dr. W the all-expenses paid trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

150. On or about April 15, 1999, Serono caused a $4,000 check for airline tickets to be issued to Dr. W, who had accepted the offer for the all-expenses paid trip to the Cannes Conference.

151. In or about March 15-19, 1999, during a presentation at Serono's National Sales meeting, Bruens announced the names of 10 physicians who were "US Invitees" to the Cannes Conference, including Dr. P in Florida; Dr. AC in New Jersey; and Drs. O, G and W in New York.

152. As a result of Serono's fraudulent and deceptive conduct, and Serono's control over each of the Physician Kickback Enterprises, physicians wrote an excessive

number of prescriptions for Serostim, and consumers and third-party payors were cause to pay for an excessive number of Serostim prescriptions, causing unfair losses to the payors and unfair profits to be garnered by Serono.

J. Gifting BIA Machines

153. During the winter and spring of 1997, Serono Labs gave doctors BIAs through the "Serono BIA Program." At first, doctors could purchase or lease the machines or accept a BIA in lieu of the grant fee Serono Labs paid the physicians for patients enrolled in an observational "study" known as "SeronAIDS" (under which Serono Labs paid them $75 per patient per quarter to report their responses to the drug) until the value of the machine was "paid off." The doctors were offered a BIA in return for placing 10 patients on Serostim and enrolling them in the SeronAIDs observational study.

154. The machines were worth about $4,000. The BIA machines were probably worth more than the fair market value of the physician's time, and were intended to induce the physicians to write excessive prescriptions for Serostim. The offer and payment of the kickbacks and inducements was intended by Serono to cause physicians to prescribe Serostim, and to cause consumers and third-party payors to pay for Serostim, in circumstances in which there was no medical necessity demonstrated, and no medical benefit conferred, on the patients taking Serostim. Serono benefited at the expense of the consumers and third-party payors in throughout the United States.

K. Defendants' Promotion of Inflated Dosages of Serostim

155. Although the recommended and most commonly prescribed dosage of Serostim was 6mg daily, Serono had learned through the experience of its sales representatives that a dose of 4mg taken every other day would generally produce the benefits sought by the 6mg daily Serostim therapy with greatly reduced or eliminated side-effects.

156. Upon information and belief, Serono sales representatives communicated their experience to Serono, but were instructed by Serono to continue to recommend 6mg daily as the optimal dosage for Serostim and to suggest prescriptions of anti-inflammatory drugs to deal with Serostim's side-effects.

157. In connection with receiving accelerated approval from the FDA to market Serostim, Serono represented that it would "further study the drug… to verify its clinical benefits including the determination of the optimal dose." Letter Thomas A. Lang, Serono's Vice President, regulatory affairs, to the FDA, dated June 27, 1996.

158. Serono however, never conducted, and indeed, consciously avoided conducting, the promised studies. Serono failed to conduct the additional studies because it knew that such studies would result in a finding that effective Serostim therapy could be achieved through administering a dosage of Serostim that was both smaller and less frequently administered than the 6mg daily dosage.

159. If a study were to establish the optimal dosage for Serostim as a 4mg dose taken three to four times per week, then the impact on Serono revenues would be substantial. As only 12-16mg of Serostim would be required weekly, rather than the current 42mg, Serono's revenues would be, at the very least, cut in half as a result of Serono conducting the promised studies. Therefore, on information and belief, the effect of Serono's knowing failure to conduct the promised studies is to cause consumers and third-party payors to pay double, if not three to four times more than, the amount necessary for effective Serostim therapy.

L. Defendants' Off-Label Marketing of Serostim

160. In addition to its other efforts to fraudulently obtain payment from consumers and third-party payors, Serono also received payment for an unauthorized "open-label study." As a result, Serono engaged in off-label marketing.

161. Serono established what it called an "open-label study" to determine the effect of Serostim on lypodystrophy, a condition that occurs in HIV patients. At the time, Serono was in the midst of FDA trials attempting to obtain orphan drug status for Seroistim for the treatment of lypodystrophy.

162. Under the protocol established by Serono for the "open-label study," participating physicians were permitted to prescribe Serostim for up to a six month period for treatment of lypodystrophy. Third-party payors were billed for prescriptions of Serostim under the "open-label study."

163. Serono directed its sales force to inform physicians about this study, assist in establishing the criteria for the study, identifying potential participants, and monitoring the patients enrolled.

164. In fact, the study was *not approved* by the FDA for evaluation of Serostim in the treatment of lypodystrophy. Consequently, the physicians who participated were, in fact, prescribing Serostim for an unapproved and unrecognized off-label use because lypodystrophy was not an FDA-approved indication for the drug.

165. Many months after the representatives had marketed Serostim for use in treating lypodrostrophy and physicians had prescribed pursuant to the purported study, the studies were terminated by order of Serono management.

M. Defendants' Other Drugs

166. The other drugs covered by this lawsuits are Cetrotide, Crinone, Gonal-F, Fertinex, Ovidrel, Pergonal, Profasi, Rebif, and Saizen.

167. Serono has products on the market in three core therapeutic areas: reproductive health, multiple sclerosis, and growth and metabolism. Recombinant technology allows the modification of cells or rapidly growing microorganisms (such as some mammalian

cells, yeast or bacteria) by introducing into a segment of their DNA a gene enabling them to produce specific proteins. Serono's products include:

168. Gonal-F is the first recombinant gonadotropin approved for treatment of infertility and is administered through subcutaneous injection..

169. Rebif is the first interferon for Multiple Sclerosis available at two dosages in a liquid pre-filled syringe, and the highest dose interferon beta available around the world.

170. Saizen is Serono's first recombinant drug to receive marketing approval, used for the treatment of growth disorders in children and is administered through injection..

171. Cetrotide is a synthetic decapeptide with gonadotropin-releasing hormone antagonistic activity and is administered through injection.

172. Crinone is a progesterone vaginal gel for use by infertile women and is administered through injection.

173. Fertinex is used to stimulate the development of multiple follicules in ovulatory patients undergoing assisted reproductive technologies such as in vitro fertilization and is administered through injection.

174. Ovidrel used in infertility treatment cycles to help follicles mature and to trigger the actual release of mature eggs from a woman's ovaries following treatment with products containing human follicle stimulating hormone and is administered through injection.

175. Pergonal is a natural purified product extracted from the urine of post-menopausal women. It is administered by intramuscular injection. The hormones in Pergonal stimulate the ovaries to develop mature follicles, which contain eggs.

176. Profasi is a purified preparation of a natural hormone called human chorionic gonadotropin that is used with fertility treatment in women, usually with other

fertility medications, to assist eggs with breaking through the follicle, or ovulate. It is administered through injection.

177. Defendants' drugs, including but not limited to Gonol-F, Serostim and Rebif, compete with other prescription drug manufacturers' products.

178. Serono created and implemented fraudulent marketing and sales schemes to substantially increase the sales of its drugs and reap unlawful profits at the expense of consumers and third-party payors. To compete, Serono offered doctors who make prescribing decisions financial inducements if they prescribed Serono's drugs. Serono concealed these inducements from consumers and third-party payors.

179. Specifically, from 1996 to the present, Serono employed deceptive and unlawful promotional tactics to increase the sales of its drugs and to reap unfair profits at the expense of consumers and third-party payors. The improper promotional practices were based on Serono's providing financial assistance, including unrestricted educational grants, stipends, travel benefits, and other unlawful remuneration, to providers including physicians, physician groups, and hospitals, to increase Serono product sales and market share by causing physicians to prescribe Serono products instead of competing products or less expensive therapies.

180. Serono's decisions to provide the purported grants and other inducements were accompanied by internal analysis concerning the "ROI," or "Return on Investment," that could be expected from the payment of the inducement. The existence of Serono's ROI analyses demonstrates that the purported grants were not grants at all, but *quid pro quo* cash payments made in exchange for pledges of loyalty to Serono products and to meet Serono product prescribing and market share goals.

181. Serono sales consultants were instructed by Serono marketing and management to identify providers to whom payment of inducements would result in increased sales of Serono products.

182. Serono sales consultants, for example, as part of developing a promotional budget, were directed to seek Custom Funds from Serono, purportedly for grant purposes, but to use at their discretion to increase sales and were instructed (emphasis in original):

> [T]his budget should be used any way you see fit to address your **best growth opportunities** in the region during 2001. I suggest that you reserve all for allocation at your discretion based on solid business opportunities and strong ROI analysis.

183. Serono sales consultants, whose explicit mission was to call on Serono product prescribers to promote *sales*, were provided with form letters to give to the physicians they called on to be used for purported unrestricted educational grant applications.

184. Serono paid substantial sums to large teaching hospitals in Massachusetts, New York, and Connecticut whose physicians prescribed Serono fertility and other products.

185. For example, in its dealings with the Massachusetts teaching hospital, Serono offered to fund a fellowship program through a purported grant in exchange for a commitment by the hospital to maintain an 80% market share in its physicians' prescription of certain Serono fertility products, and a future commitment to use Serono's new products. Understanding the illegality of these arrangements and seeking to conceal them, Serono insisted that all commitments be kept "verbal" and that they not be put in writing. Serono's internal analysis of the purported proposed grant included precise Serono product utilization data by the hospital, competitor data, market share goals, and ROI analysis, but was bereft of all but the most minimal description of the educational purpose to which the purported grant funds will be put.

186. In its dealings with the New York teaching hospital, Serono negotiated a purported research grant of $200,000 to fund the construction of a specialized laboratory. Serono's proposal was made in order to differentiate itself from competitors and to "develop a partnership that was mutually beneficial."

187. In its dealings with the Connecticut teaching hospital, Serono's funding of marketing support and studies was based exclusively on precise prescription, revenue, and competitive market share data.

188. Serono entered into similar arrangements with physician clinics in Massachusetts and elsewhere, where funding was provided to clinics for market expansion, referral programs, and nursing and staff education based on the ROI to Serono.

189. Serono also funded excessive speaking and advisory contracts with physicians in Colorado and elsewhere as part of its promotional activity.

190. As a result of the concealed and unjustified travel stipends, financial assistance, unrestricted educational grants, and other unlawful remuneration paid by Serono to physicians who prescribed Serono drug products, Serono caused excessive and medically unnecessary Serostim prescriptions to be written, resulting in unnecessary and excessive payments by consumers and third-party payors. Serono benefited at the expense of the consumers and third-party payors in the United States.

V. CLASS ACTION ALLEGATIONS

191. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of itself and the Class comprised of:

> All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for Cetrotide, Crinone, Gonal-F, Fertinex, Ovidrel, Pergonal, Profasi, Rebif, Saizen, or Serostim.[1]

Excluded from the Class are: (a) each defendant and any entity in which any defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors; (b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the Class Period. Included in the Class are end payors and consumers who made a pro rata co-payment or who paid cash.

192. The Class Period is January 1, 1996 to the present.[2]

193. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

194. The claims of the representative plaintiff are typical of the claims of the Class, as required by Rule 23(a)(3), in that the representative plaintiff is an entity who, like all Class Members, as a result of defendants' deceptive and unlawful scheme, paid for drugs that were medically unnecessary and unbeneficial as a result of prescriptions that were based on diagnostic devices that were scientifically unproven or made or influenced by the payment of an inducement. The representative plaintiffs, like all Class Members, has been damaged by defendants' misconduct because, among other things, they paid for drugs that were not mecially necessary or beneficial and that they would not have paid for but for defendants' improper actions.

[1] Plaintiff reserves the right to modify the Class Definition based on class related discovery and/or merits discovery.

[2] The exact dates for the Class Period may be refined based upon discovery.

195. The Class representatives for the Class are the only plaintiffs.

196. The factual and legal bases of each defendant's misconduct are common to the Class Members and represent a common thread of fraud and other illegal misconduct resulting in injury to plaintiff and members of the Class.

197. There are many questions of law and fact common to plaintiff and the Class, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

a. Whether defendants promoted the use of unapproved, adulterated and unproven medical devices and computer software and distributed these devices to physicians.

b. Whether defendants trained, authorized and encouraged sales representatives to administer the purported body cell mass wasting tests to AIDS victims to fraudulently induce physicians to prescribe Serostim.

c. Whether Serono sales consultants manipulated the results of the fraudulent purported body cell mass wasting tests administered to AIDS victims to fraudulently induce physicians to prescribe Serostim.

d. Whether defendants' fraudulent and unlawful promotion of unapproved, adulterated and unproven medical devices and computer software caused consumers and third-party payors to pay for Serostim which the patients did not need and which provided them no benefit.

e. Whether defendants fraudulently encouraged physicians to prescribe Serostim in quantities that their patients did not need or could not consume;

f. Whether defendants had physicians sign blank prescription forms for Serono sales representatives to complete and ordered Serostim under falsified physician signatures;

g. Whether defendants' participation in activities involving the excessive ordering of Serostim caused consumers and third-party payors to pay for Serostim in circumstances in which there was no medical necessity demonstrated, and no medical benefit conferred, on the patients taking Serostim, or in which it was not used at all.

h. Whether the defendants paid illegal inducements and kickbacks to physicians to induce them to prescribe Serostim;

i. Whether the offer and payment of the kickbacks and inducements was intended by Serono to cause and did cause physicians to prescribe Serostim, and was intended to cause and did cause consumers and third-party payors to pay for Serostim, in circumstances in which there was no medical necessity demonstrated, and no medical benefit conferred, on the patients taking Serostim.

j. Whether defendants marketed Serostim to physicians for the treatment of lipodystrophy, a separate condition involving weight gain in the mid-section and weight loss in the extremities, for which Serostim was not approved by the FDA;

k. Whether the prescriptions of Serostim for treatment of lipodystrophy were supported by medical necessity and conferred medical benefit.

l. Whether defendants engaged in a pattern of deceptive and/or fraudulent activity intended to deceive and/or defraud plaintiffs and the Class Members;

m. Whether defendants are liable to plaintiffs and the Class Members for damages for conduct actionable under the various state consumer protection statutes;

n. Whether defendants are liable to plaintiffs and the Class Members for damages for conduct actionable under various state law provisions for unjust enrichment.

o. Whether defendants engaged in a pattern and practice of unlawful acts that caused plaintiffs and Class Members to make payments for products which patients did not need;

p. Whether defendants engaged in a pattern of deceptive and unlawful activity intended to defraud plaintiffs and the Class Members;

q. Whether defendants are liable to plaintiffs and the Class Members for damages for conduct actionable under Chapter 93A and various other state consumer protection statutes; and

r. Whether defendants are liable to plaintiffs and the Class Members for damages for conduct actionable under various state law provisions for unjust enrichment.

198. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither plaintiffs nor their counsel have any interest adverse to those of the Class.

199. Plaintiffs and members of the Class have all suffered, and will continue to suffer, harm and damages as a result of defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, defendants have acted and failed to act on grounds generally applicable to plaintiff and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

VI. CAUSES OF ACTION

COUNT I: THE SEROSTIM MEDICAL DEVICE ENTERPRISE: VIOLATION OF 18 U.S.C § 1962

200. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

201. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of enterprise, the Serostim Medical Device Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

202. The Defendants Serono, RJL, and Liedtke participated in associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Serono, including its employees and agents, RJL, Liedtke, and other persons unknown. The Serostim Medical Device Enterprise was an ongoing organization that functioned as a continuing unit. The enterprise was created and used as a tool to effectuate a pattern of unlawful racketeering activity. The Defendants are "persons" distinct from the enterprise.

203. Defendants and the other members of the Serostim Medical Device Enterprise knowingly and willfully created and maintained systematic links for a common purpose: to aid in the unlawful promotion of Serostim for medically unnecessary and unbeneficial purposes based on use of medical devices and software that had not been scientifically validated in order to fraudulently increase the number of Serostim prescriptions and, as a result, purchases. Each of the participants in the enterprise received substantial revenue from the illegal scheme to promote Serostim. Such revenue was greater than it would have been if Serostim had been marketed lawfully. All participants were aware of defendants' control over the activities of the Serostim Medical Device Enterprise. All participants knew that the objective of the conspiracy and the enterprise was illegal and deceptive. Furthermore, each portion of the Serostim Medical Device Enterprise benefited from the existence of other parts.

204. The Serostim Medical Device Enterprise engaged in and affected interstate commerce, because, among other things, it marketed, sold, purchased, or provided Serostim to thousands of individuals throughout the United States.

205. Defendants have exerted control over the Serostim Medical Device Enterprise and management of the affairs of the Serostim Medical Device Enterprise.

206. Defendants have conducted and participated in the affairs of the Serostim Medical Device Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud) and U.S.C. § 1343 (wire fraud).

207. Defendants distributed the adulterated, unproven, and unapproved medical devices and associated software in interstate commerce and used mail and interstate wire communications and interstate travel to create and manage the fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed the deployment of sales representatives, and impacted victims, across the country.

208. Defendants' use of the mails and wires to perpetrate the fraud involved communications, including, but not limited to:

a. marketing materials and training resulting in diagnostic training that was known by defendants not to be unapproved and scientifically unproven, resulting in prescriptions for Serostim that were not medically necessary or beneficial, including materials sent to doctors across the country;

b. communications with physicians that fraudulently misrepresented the medical conditions for which Serostim could be prescribed;

c. communications with consumers and third-party payors inducing

payments for Serostim to be made based on misrepresentations concerning the medical necessity and usefulness of Serostim; and

d. receiving the proceeds of defendants' improper scheme.

209. In addition, Serono's corporate offices in Massachusetts have communicated by United States mail, telephone, and facsimile with various sales directors and pharmaceutical representatives, physicians, with RJL and Liedtke, and others unknown in furtherance of defendants' scheme.

210. Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under U.S.C. § 1343. Defendants' fraudulent scheme consisted of, inter alia: using adulterated equipment and software to deliberately misrepresent the conditions for which Serostim was necessary so that plaintiffs and members of the Class paid for Serostim to treat symptoms for which it was not necessary or beneficial; and actively concealing and causing others to conceal information about the true necessity of Serostim to treat patients suffering from AIDS.

211. In implementing its fraudulent scheme, defendants were acutely aware that plaintiff and members of the Class depended on the honesty and integrity of defendants in representing the medical necessity and benefit of Serostim's uses to physicians and to plaintiffs and those similarly situated in treating AIDS wasting. It is impractical and unduly expensive for the Class Members or the physicians who treated them to perform their own medical device and computer software testing or assemble all known medical evidence relating to Serostim's necessity and benefit. Class Members also rely on federal law obligating defendants to provide fair and balanced information about their drug products and the medical devices they promote to determine the necessity of using such products and

reasonably presume that medical devices promoted by defendants' are unadulterated, approved, and proven for their intended use and that defendants' testing of the medical devices and associated software and Serostim complied with defendants' obligations under federal law. Defendants knew that their scheme was unlawful and fraudulent in that it was based on the use of adulterated, unapproved, and unproven medical devices, caused physicians to prescribe Serostim in circumstances in which it was neither necessary nor beneficial, and caused consumers and third-party payors to pay excessive amounts for Serostim in circumstances in which it was neither necessary nor beneficial.

212. Defendants' scheme was calculated to ensure that plaintiffs and the Class would pay for Serostim for medically unnecessary and unbeneficial purposes. Consumers and third-party payors were injured in their property by reason of these violations by, among other things, having to pay hundreds of million of dollars for Serostim prescriptions that they would not have otherwise have paid and that were neither medically necessary nor medically beneficial.

213. The conduct of the Serostim Medical Device Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for the Serostim Medical Device Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

214. Defendants' fraudulent marketing scheme depended upon its concealing its use of unapproved and adulterated medical devices and software and unproven testing from physicians, consumers and third-party payors. These activities and others described above concealed defendants' fraudulent promotional activities and consumers and third-party payors

could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence.

215. The earliest Plaintiffs could have reasonably become aware of the fraudulent marketing scheme was 2005.

216. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of defendants' conduct. Accordingly, defendants are estopped from relying on any statute of limitations to defeat any of plaintiffs' claims.

217. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including plaintiffs and the members of the Class.

218. Plaintiffs and members of the Class have been injured in their business and property by reason of these violations in that plaintiffs and members of the Class have made millions of dollars in payment for Serostim that they would not have made had Defendants not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by defendants, plaintiffs and the Class have suffered ascertainable loss and damages.

219. Plaintiffs' and members of the Class' injuries were directly and proximately caused by defendants' racketeering activity as described above.

220. By virtue of these violations of 18 U.S.C. § 1962(c), defendants are liable to Plaintiffs and the Class for three times the damages plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT II: THE SEROSTIM PHYSICIAN KICKBACK ENTERPRISE: VIOLATION OF 18 U.S.C § 1962(C)

221. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

222. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprises, the Serostim Physician Kickback Enterprises, through a pattern of unlawful racketeering activity in violation of 18 U.S.C. § 1962(c).

223. The defendants participated in associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Serono, its employees, physicians.,, and other persons unknown. The Serostim Physician Kickback Enterprises were an ongoing organizations that functioned as individual continuing units. The enterprises were created and used as tools to effectuate a pattern of racketeering activity. The defendants are "persons" distinct from the enterprises.

224. Defendants and the other members of the Serostim Physician Kickback Enterprises knowingly and willfully created and maintained systematic links for a common purpose: to aid in the unlawful promotion of Serostim for medically unnecessary and unbeneficial purposes. Each of the participants in each of the enterprises received substantial revenue from the scheme to promote Serostim. Such revenue was greater than it would have been if Serostim had been was marketed lawfully. Serono controlled each of the Physician Kickback Enterprises by determining which individual physicians would be paid inducements, and by making the payments of such inducements. Each of the participants was aware of

defendants' control over the activities of the Serostim Physician Kickback Enterprises. All participants knew or should have known that the objective of the conspiracy and the enterprise was illegal and deceptive. Furthermore, each portion of each of the Serostim Physician Kickback Enterprises benefited from the existence of other parts.

225. The Serostim Physician Kickback Enterprises engaged in and affected interstate commerce, because, among other things, they involved interstate travel and communications among the members of the enterprises, generated interstate mail and wire communications, and resulted in Serostim being sold, purchased, or provided to individuals throughout the United States.

226. Defendants have exerted control over the Serostim Physician Kickback Enterprises and management of the affairs of the Serostim Physician Kickback Enterprises.

227. Defendants have conducted and participated in the affairs of the Serostim Physician Kickback Enterprises through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud) and U.S.C. § 1343 (wire fraud).

228. Defendants have used interstate travel and mail and interstate wire communications to create and manage the fraudulent scheme. Defendants' scheme involved a national marketing campaign, referred to as the "$6m-6 Day Plan," and encompassed the deployment of sales representatives to meet and communicate with physicians across the country. Defendants' use of the mails and wires to perpetrate the fraud involved communications, including, but not limited to:

a. telephonic communications and travel for in-person meetings to induce and did induce the excessive prescription of Serostim not based on medical necessity or medicial benefit;

b. voicemail messages conferring offers;

c. transmission of airplane tickets and wire payments and reimbursements, as inducements for the medically unnecessary and unbeneficial prescription of Serostim;

d. transmission of other financial benefits to the physicians relating to the medically unnecessary and unbeneficial prescription of Serostim;

e. communications intended to conceal from consumers and third-party payors the existence of the payment of kickbacks in exchange for unnecessary Serostim prescriptions and the existence of the Physician Kickback Enterprises; and

f. Receiving the proceeds of defendants' improper scheme.

229. In addition, defendants' corporate offices communicated by United States mail, telephone, and facsimile with sales executives, directors, and consultants in furtherance of defendants' scheme.

230. Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under U.S.C. § 1343. Defendants' fraudulent scheme consisted of, among other things, paying inducements to physicians in exchange for agreements to prescribe Serostim irrespective of medical necessity or benefit.

231. In implementing their fraudulent schemes, defendants were acutely aware that plaintiff and members of the Class depended on the honesty and integrity of defendants in representing the medical necessity of Serostim's uses to plaintiffs and other consumers and third-party payors who constitue the Class,and the absence of non-medical inducements for the prescription of Serostim.. It is impractical and unduly expensive for the Class Members to

investigate the inducements paid and exchanged as a consequence of the actions of the Physician Kickback Enterprises. Class Members also rely on federal law obligating defendants to promote and prescribe Serostim in a manner that complies with federal law.

232. Defendants' schemes were calculated to ensure that Plaintiffs and the Class would pay for Serostim for medically unnecessary and unbeneficial purposes. Defendants, defendants' sales representatives, and the physicians knew that the schemes were unlawful and fraudulent in that they were based on the use of illegal kickbacks and inducements. Defendants schemes further caused consumers and third-party payors to pay for excessive amounts of Serostim in circumstances in which it was neither necessary nor beneficial.

233. The conduct of the Serostim Physician Kickback Enterprises described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for each of the Serostim Physician Kickback Enterprises to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

234. Defendants' fraudulent marketing schemes depended upon concealing the illegal payments to each physician and the physicians' agreement to attain prescription goals from consumers and third-party payors. These activities and others described above concealed defendants' fraudulent promotional activities and consumers and third-party payors could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence.

235. The earliest plaintiffs could have reasonably become aware of the fraudulent marketing scheme was 2005.

236. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of defendants' conduct. Accordingly, defendant is estopped from relying on any statute of limitations to defeat any of plaintiffs' claims.

237. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including plaintiffs and the members of the Class.

238. Plaintiffs and members of the Class have been injured in their business and property by reason of these violations in that plaintiffs and members of the Class have made millions of dollars in payment for Serostim that they would not have made had defendants not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by defendant, Plaintiffs and the Class have suffered ascertainable loss and damages.

239. Plaintiffs' and members of the Class' injuries were directly and proximately caused by defendants' racketeering activity as described above.

240. By virtue of these violations of 18 U.S.C. § 1962(c), defendants are liable to plaintiffs and the Class for three times the damages plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT III: VIOLATION OF U.S.C. § 1962(D) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C)

241. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

242. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

243. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the enterprises described previously through a pattern of racketeering activity.

244. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the Class of money.

245. The nature of the above-described defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing fraudulent and illegal acts have been and are part of an overall pattern of racketeering activity.

246. As a direct and proximate result of defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiffs and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

247. Defendants sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346.

248. Defendants' violations of the above federal laws and the effects thereof detailed above continued over a course of time. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and members of the Class have made millions of dollars in payments for Serostim that they would not have made had defendants not conspired to violate 18 U.S.C. § 1962(c).

249. By reason of the unlawful acts engaged in by defendants, plaintiffs and the Class have suffered ascertainable loss and damages. Injuries suffered by plaintiffs and members of the Class were directly and proximately caused by defendants' racketeering activity as described above.

250. By virtue of these violations of 18 U.S.C. § 1962(d), defendants are liable to Plaintiffs and the Class for three times the damages plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT IV: CIVIL CONSPIRACY

251. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

252. The defendants joined in a conspiracy to promote, distribute, and use adulterated, unapproved, and unproven medical devices and software for the purpose of conducting fraudulent body cell mass wasting tests in order to cause physicians to prescribe

Serostim without medical need or medical benefit, and to provide illegal financial incentives to physicians for the purpose of causing excessive and medically unnecessary prescriptions to be written for Serostim and other Serono products.

253. The defendants consciously conspired and deliberately pursued a common plan or design to commit tortious acts, subjecting each to joint liability.

254. Defendants each committed an unlawful act or acts in furtherance of this conspiracy, including acts violating state consumer protection laws and the common law. All of these acts were in furtherance of the conspiracy.

255. Plaintiffs are entitled to a presumption of reliance on the false representations, concealments and nondisclosures by the defendants. Class members were ignorant of defendants' conduct and were ignorant of the full and true facts suppressed by them, and such reliance was justified.

256. As a direct, proximate result of this conspiracy, plaintiff and the Class have been injured, as they have suffered and continue to suffer economic losses and general and specific damages, all in an amount to be determined according to proof.

COUNT V: VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT

257. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

258. Pursuant to the Chapter 93A, defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the promotion and sale of its prescription drug products to plaintiffs and the class. Defendants failed to refrain from such conduct, and engaged in willful and knowing unfair and deceptive conduct in connection with the promotion and sale of its pharmaceutical products.

259. As a proximate result of defendants' conduct, consumers and third-party payors paid for prescriptions of Serono products that were neither medically necessary nor beneficial to patients, thus suffering an injury within the meaning of Chapter 93A.

260. The losses suffered by consumers and third-party payors were a foreseeable consequence of defendants'conduct.

261. Defendants' wrongful acts occurred primarily and substantially in Massachusetts.

262. Plaintiffs have made demand on defendants as required by c. 93A.

263. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and members of the Class are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

COUNT VI: VIOLATION OF STATE CONSUMER PROTECTION STATUTES

264. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

265. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they concealed that their use of medical devices and associated software were not approved or scientifically proven for diagnosis of AIDS wasting, that they made illegal payments to physicians in exchange for gaining commitments to prescribe Serostim and other Serono products, that they made illegal payments to pharmacies in exchange for gaining commitments to alter prescriptions or provide information to be used by the defendants, in fraudulently promoting Serostim, and generally concealed their knowledge that they were prescriptions for Serostim that were medically unnecessary based on testing that had not been

proven to be scientifically valid. As a direct result of defendants' deceptive, unfair, unconscionable, and fraudulent conduct, plaintiffs and members of the Class were injured in that they paid millions of dollars for Serostim and other Serono products that they would not have paid had defendants not engaged in unfair and deceptive conduct.

266. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 44-1522, et seq.

267. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, et seq.

268. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.

269. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et seq.

270. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.

272. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.

273. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, et seq.

274. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.

275. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §10-1-392, et seq.

276. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.

277. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.

278. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 50511, et seq.

279. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, et seq.

280. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1 b, et seq.

281. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.

282. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.

283. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.

284. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.

285. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.

286. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, et seq.

287. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.010, et seq.

288. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.

289. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.

290. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.

291. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.

292. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, et seq.

293. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, et seq.

294. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 et seq.

295. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.

296. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.

297. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

298. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.

299. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.

300. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.

301. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, et seq.

302. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.

303. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. code Laws § 37-24-1, et seq.

304. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.

305. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.

306. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, et seq.

307. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, et seq.

308. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.

309. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, et seq.

310. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.

311. The unfair and deceptive acts and practices of defendants have directly, foreseeably, and proximately caused damages and injury to plaintiffs and the members of the Class.

312. The actions and failures to act of defendants, including the false and misleading representations and omissions of material facts regarding the lack of proven medical necessity or benefit of Serostim and nondisclosure of kickbacks with respect to Serostim and other Serono products and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses, or employment by defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of defendants in violation of the consumer protection statutes listed above

313. Physicians, consumers, and third-party payors relied upon defendants' misrepresentations and omission in prescribing Serostim and other Serono products to patients. By reason of the unlawful acts engaged in by defendants, plaintiffs and the Class have suffered ascertainable loss and damages. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and the Class were damaged by paying for these prescriptions.

314. As a direct and proximate result of defendants' wrongful conduct, Plaintiffs and members of the Class are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

COUNT VII: COMMON LAW FRAUD

315. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

316. Defendants used unapproved and unproven medical devices and software, conducted fraudulent and misleading tests, and manipulated and fabricated test results, in order to generate data which would induce physicians to prescribe Serostim in circumstances where it was neither medically necessary nor beneficial.

317. Defendants made misrepresentations and omissions of facts material to plaintiffs' and the Class, including deliberately misrepresenting the medical necessity and benefit of using Serostim, deliberately omitting to disclose information concerning the lack of scientific validation for their adulterated and unapproved medical device testing process, and other misrepresentations and omissions as set forth herein.

318. Defendants knew at the time that they made these misrepresentations and omissions that they were false or that defendants had failed to disclose facts it was obligated to disclose in order to make its other representations not misleading. Defendants was aware that physicians, consumers, and third-party payors would rely on these misrepresentations and omissions in making prescribing payment, and reimbursement.

319. Defendants also failed to disclose to consumers and third-party payors that they had made payments in the form of unrestricted educational grants, travel stipends, and other inducements, in exchange for obtaining prescriptions of Serono products. Failure to

disclose the existence of these payments, all terms concerning them, and their purposes, constitutes a material omission by defendants.

320. Plaintiffs and the Class reasonably relied upon defendants' misrepresentations and omissions of material fact. Plaintiffs and the Class had no reason to doubt the veracity or scientific validity of the testing procedures defendants promoted through their marketing and sales strategies.

321. Defendants' misrepresentations and omissions of material fact directly and proximately caused Plaintiffs' and the Class's damages.

322. Consumers and third-party payors relied on the fraudulent tests and the prescriptions that resulted in paying for Serostim and other Serono products, and were injured as a result. By virtue of the fraud they perpetrated on plaintiffs and the Class, defendants are liable to plaintiffs and the Class for all damages plaintiffs and the Class have sustained, plus punitive damages, plus the cost of this suit, including attorney's fees.

COUNT VIII: UNJUST ENRICHMENT

323. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

324. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, defendants have profited and benefited from payments plaintiffs and the Class made for Serostim and the other Serono prescription drug products set forth in the complaint.

325. In exchange for the payments they made for Serostim, and at the time they made these payments, plaintiffs and the Class expected that the drug was medically necessary and beneficial for the condition for which it was prescribed and the determination of medical necessity was made based on approved and valid testing processes.

326. As an intended and expected result of the concealed and unjustified travel payments, financial assistance, unrestricted educational grants, and other unlawful remuneration paid by Serono to providers who prescribed Serono drug products, Serono caused excessive and medically unnecessary prescriptions to be written for Serostim and other Serono products, resulting in unnecessary payments by consumers and third-party payors.

327. Defendants have voluntarily accepted and retained the benefit of these payments with full knowledge and awareness that, as a result of their wrongdoing, plaintiffs and the Class paid for Serostim and other Serono products when they otherwise would not have done so. The failure of defendants to provide plaintiffs and the Class with the remuneration they expected enriched defendants unjustly.

328. Plaintiffs and the Class are entitled in equity to seek restitution of defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

VII. DEMAND FOR RELIEF

329. WHEREFORE, plaintiffs and the Class demand judgment against defendants in each claim for relief, jointly and severally, as follows:

a. On plaintiffs' and the Class's RICO claims, three times the damages plaintiffs and the Class have sustained as a result of defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

b. On plaintiffs' conspiracy claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus plaintiffs' cost in this suit, including all reasonable attorneys' fees;

c. On plaintiffs' 93A claim, compensatory damages, three times the damages plaintiffs and the Class have sustained as a result of defendants' conduct, such as amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorney's fees;

d. On plaintiffs' and the Class's consumer fraud act claims, compensatory damages, three times the damages plaintiffs and the Class have sustained as a result of defendants' conduct, such as amount to be determined at trial, plus plaintiffs' costs in this suit, including reasonable attorney's fees;

e. On plaintiffs' and the Class's common law fraud claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus Plaintiffs' cost in this suit, including all reasonable attorneys' fees;

f. On plaintiffs' and the Class's claim for unjust enrichment, recovery in the amount of plaintiffs' and the Class's payment for Serostim based on prescriptions that supported by tests using invalid unapproved medical devices and software, or based on prescriptions that were not supported by medical necessity or benefit, such amount to be determined at trial; and all sums received by Serono as a result of the concealed and unjustified travel payments, financial assistance, unrestricted educational grants, and other unlawful remuneration paid by Serono to providers who prescribed Serostim and other Serono drug products, plus plaintiffs' costs in this suit, including all reasonable attorney's fees;

g. Awarding plaintiffs and the Class other appropriate equitable relief;

h. Awarding plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

i. Awarding plaintiffs and the Class such other and further relief as may be just and proper under the circumstances.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) Plaintiffs demand a trial by jury on all issues so triable.

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Dated March 21, 2006

CERTIFICATE OF SERVICE

Docket No. MDL 1456

I, David S. Nalven, hereby certify that I am one of plaintiffs' attorneys and that, on March 21, 2006, I caused copies of Plaintiffs' Second Amended Class Action Complaint Against Serono International, S.A., Serono Laboratories, Inc., Serono, Inc., RJL Systems, Inc. and Rudoph J. Liedtke to be served via VeriLaw on all counsel of record in this proceeding via Lexis/Nexis File Serve.

/s/ David S. Nalven

Dated: March 21, 2006